

107TH CONGRESS  
1ST SESSION

# H. R. 3066

To amend the Federal Food, Drug, and Cosmetic Act to establish labeling and advertising requirements for dietary supplements containing ephedrine alkaloids, to prohibit sales of such supplements to individuals under the age of 18, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 9, 2001

Mrs. DAVIS of California introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish labeling and advertising requirements for dietary supplements containing ephedrine alkaloids, to prohibit sales of such supplements to individuals under the age of 18, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Ephedrine Alkaloid  
5 Consumer Protection Act”.

1 **SEC. 2. REQUIREMENTS REGARDING DIETARY SUPPLE-**  
2 **MENTS CONTAINING EPHEDRINE ALKALOIDS.**

3 (a) **FOOD LABELING AND ADVERTISING.**—Section  
4 403 of the Federal Food, Drug, and Cosmetic Act (21  
5 U.S.C. 343) is amended by adding at the end the fol-  
6 lowing:

7 “(t) If it is a dietary supplement containing ephed-  
8 rine alkaloids, unless its labeling and advertising are in  
9 accordance with the following, as applicable:

10 “(1) The label bears, in at least  $\frac{1}{16}$  inch type,  
11 a notice as follows:

12 ‘WARNING: (A) Not for use by individ-  
13 uals under the age of 18. Do not use if preg-  
14 nant or nursing. Consult a physician or licensed  
15 qualified health care professional before using  
16 this product if you have, or have a family his-  
17 tory of, heart disease, thyroid disease, diabetes,  
18 asthma, high blood pressure, recurrent head-  
19 aches, depression or other psychiatric condition,  
20 glaucoma, difficulty in urinating, prostate en-  
21 largement, or seizure disorder, or if you are  
22 using monoamine oxidase inhibitor (MAOI) or  
23 any other dietary supplement, prescription  
24 drug, or over-the-counter drug containing  
25 ephedrine, pseudoephedrine, caffeine, or phenyl-  
26 propanolamine (ingredients found in certain al-

1           lergy, asthma, cough or cold, and weight control  
2           products).

3           ‘(B) Consuming this product may cause se-  
4           rious adverse health effects, including heart at-  
5           tack, stroke, and death.

6           ‘(C) Discontinue use and call a physician  
7           or licensed qualified health care professional im-  
8           mediately if you experience rapid heartbeat, diz-  
9           ziness, severe headache, shortness of breath, or  
10          other similar symptoms.

11          ‘(D) Individuals who consume additional  
12          caffeine with this product may experience seri-  
13          ous adverse health effects.

14          ‘(E) This product contains \_\_\_\_ milli-  
15          grams concentrated ephedrine group alkaloids  
16          per serving in the form of herbal extracts.’.

17          In lieu of the blank, the number of milligrams shall  
18          be identified.

19          “(2) The label bears standardized nomenclature  
20          for the ephedrine ingredient such that the ephedrine  
21          group alkaloid name is used when referring to the  
22          active ingredients in place of or in addition to the  
23          botanical name of the ephedrine group alkaloid.

24          “(3) The label bears the amount in milligrams  
25          of caffeine alkaloids and other ingredients per serv-

1       ing that have a known stimulant effect (ex yohim-  
2       bine).

3               “(4) The label bears the toll-free telephone  
4       number, and the address of the Internet site, main-  
5       tained by the Secretary for purposes of the medical  
6       product reporting program (MedWatch or any suc-  
7       cessor program).

8               “(5) The labeling (other than the label), and all  
9       prerecorded or scripted radio or television adver-  
10      tising, provide a notice as follows: ‘This product con-  
11      tains ephedrine group alkaloids and may cause seri-  
12      ous adverse health effects. Read the label and follow  
13      directions.’”.

14      (b) SALES TO MINORS.—Chapter IV of the Federal  
15      Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.)  
16      is amended by inserting after section 403C the following  
17      section:

18               “SALE OF DIETARY SUPPLEMENTS CONTAINING  
19                               EPHEDRINE ALKALOIDS

20               “SEC. 403D. The sale of a dietary supplement con-  
21      taining ephedrine alkaloids shall be deemed to be an act  
22      that results in such supplement being misbranded while  
23      held for sale if—

24               “(1) the sale of the supplement is made to an  
25      individual under the age of 18; or

1           “(2) in the case of a sale at retail, the pur-  
2           chaser has direct access to the supplement at the re-  
3           tail establishment involved, rather than the supple-  
4           ment being held at a portion of the establishment  
5           not intended to be accessible to customers of the es-  
6           tablishment.”.

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